DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 27, 2015

Medline Industries, Inc.
Stephanie Blair
Regulatory Affairs Specialist
One Medline Place
Mundelein, IL 60060

Re: K150286
Trade/Device Name: Medline Enteral Feeding Sets
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: PIF, KNT
Dated: April 13, 2015
Received: April 14, 2015

Dear Stephanie Blair,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150286

Device Name
Medline Enteral Feeding Sets

Indications for Use *(Describe)*

Medline Enteral Feeding Sets are intended to dispense liquid nutrition (feeding solutions) at a user controlled rate. These enteral feeding sets interface with a patient's feeding tube and may use gravity or an enteral feeding pump to dispense feeding solution. The enteral feeding sets may include a bag to contain the feeding solution and/or spike to connect to a pre-filled container.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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TRADTIONAL 510(k) SUMMARY
[AS REQUIRED BY 21 CFR 807.92(a)]

SUBMITTER / 510(k) SPONSOR

Medline Industries, Inc.
One Medline Place
Mundelein, IL 60060
Registration Number: 1417592

CONTACT PERSON

Stephanie Blair
Regulatory Affairs Specialist
Phone: 847-643-3690
Email: SBlair@medline.com

SUMMARY PREPARATION DATE

April 22, 2015

TYPE OF 510(k) SUBMISSION

Traditional

DEVICE NAME / CLASSIFICATION

Trade/Proprietary Name: Medline Enteral Feeding Sets
Common Name: Tubes, Gastrointestinal and Accessories
Classification Name: Gastrointestinal Tubes with Enteral Specific Connectors
Product Code: PIF / KNT
Device Class: II
Classification Regulation: 21 CFR 876.5980
Classification Panel: Gastroenterology and Urology

PREDICATE DEVICE

Generica Medical International Enteral Feeding Sets (K133077)

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INDICATIONS FOR USE

Medline Enteral Feeding Sets are intended to dispense liquid nutrition (feeding solutions) at a user controlled rate. These enteral feeding sets interface with a patient's feeding tube and may use gravity or an enteral feeding pump to dispense feeding solution. The enteral feeding sets may include a bag to contain the feeding solution and/or spike to connect to a pre-filled container.

DEVICE DESCRIPTION

Medline Enteral Feeding Sets consist of the following three configurations:

1.) Medline Enteral Feeding Pump Bag Set (1000ml)
2.) Medline Enteral Feeding Pump Spike Set
3.) Medline Enteral Feeding Gravity Bag Set (1000ml)

The Medline Enteral Feeding Pump Bag Set (1000ml) is designed for use with Alcor Sentinel® and Nestle Compat® enteral feeding pump systems and features a 1000ml formula bag with 100ml graduations and a protective closure cap.

The Medline Enteral Feeding Gravity Bag Set (1000ml) uses the free flow of gravity to dispense enteral feeding solutions and features a 1000ml formula bag with 100ml graduations and a protective closure cap.

The Medline Enteral Feeding Pump Spike Set features a piercing spike used to connect the set to a pre-filled container of enteral feeding solution. It is designed for use with Alcor Sentinel® and Nestle Compat® enteral feeding pump systems.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

Medline Enteral Feeding Sets are single-use, non-sterile and disposable enteral feeding sets consiting of an enteral feeding bag, tubing, drip chamber, piercing spike, roller clamp and Distal Tip ENFit connectors. The intended use and function of Medline Enteral Feeding Sets are identical to that of the predicate. In addition, Medline Enteral Feeding Sets are offered in the same design style configurations (pump bag set, spike set, and gravity bag set) and are constructed of the same materials as the predicate.

Variation from the predicate device exists only in the replacement of the predicate's 4-Step Distal Tip Connector with the subject's Distal Tip ENFit connector tested in accordance with ISO 80369-1. The addition of the ENFit connector to Medline Enteral Feeding Sets is intended to improve device performance and safety by addressing the risk of misconnections. In addition, this variation in connector design is part of an industry-wide effort to adopt a uniform connector for enteral devices that meets the requirements of ISO 80369-1 and is in accordance with FDA Draft Guidance for Industry: *Safety*

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Considerations for 510(k) Submissions to Mitigate the Risks of Misconnections with Small-bore Connectors Intended for Enteral Applications (July 27, 2012).

Biocompatibility, chemical and functional performance testing were conducted to evaluate Medline Enteral Feeding Sets with the ENFit connector incorporated into its design. The results of these tests have demonstrated that the replacement of the predicate's 4-step Distal Tip connector with the proposed device's ENFit connector does not alter the function or performance of the devices and does not raise additional questions or compromise the safety and/or effectiveness of the device. This testing, along with the various supporting data provided in this pre-market notification, establishes that Medline Enteral Feeding Sets are substantially equivalent to the predicate device.

SUMMARY OF PERFORMANCE TESTING

The following performance testing was conducted on Medline Enteral Feeding Sets:

- Enteral Connector Misconnection Assessment Study
- Human Factors Validation Study: Enteral Connectors Final Report
- PG-Lock Misconnection Data with Failure Modes and Effects Analysis (FMEA)
- Performance Testing with and without Reference Connectors:
    - Falling Drop Positive Pressure Liquid Leakage
    - Stress Cracking
    - Resistance to Separation from Axial Load
    - Resistance to Separation from Unscrewing
    - Resistance to overriding
    - Disconnection by unscrewing
- ENFit Component Verification Testing
- ENFit Bond Strength Testing
- Risk Analysis
- Pump Compatibility Testing – against predicate
- Flow Rate Testing – against predicate
- ENFit Connection Strength Testing
- Bioburden Testing –against predicate
- Cross Cavity Metrology Testing

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- Leachable and Extractable (L&E) Profile Analysis with comprehensive Toxicological Health Risk Assessment
- Biocompatibility Testing:
    - Cytotoxicity – MEM elution per ISO 10993-5;
    - Irritation – Intracutaneous reactivity per ISO 10993-10; and
    - Delayed-Type Hypersensitivity (Sensitization) – Guinea Pig Maximization Test per ISO 10993-10.

SUMMARY OF CLINICAL TESTING

Not applicable.

SUMMARY OF ANIMAL TESTING

Not applicable.

CONCLUSION

In accordance with 21 CFR Part 807, and based on a comparison of the Indications for Use, technological characteristics, and performance data to the predicate, Medline Industries, Inc. concludes that the Medline Enteral Feeding Sets are safe, effective and substantially equivalent to the predicate.